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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,540	09/18/2003	Jeffrey Roose	1671-0270/DEP-5109	4279

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EXAMINER

CABRERA, ZOILA E

ART UNIT	PAPER NUMBER
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2125

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/664,540

Applicant(s)

ROOSE, JEFFREY

Examiner

Zoila E. Cabrera

Art Unit

2125

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/16/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7, 9-13, 15, 17, 18-20, 22-26, and 28 rejected under 35 U.S.C. 102(b) as being anticipated by **Kennedy (5,360,446)**.

As for claim 1, **Kennedy** discloses, a method of making an acetabular prosthesis (Fig. 4A, acetabular 86) comprising the steps of:

- acquiring a first set of data defining in three dimensions at least a portion of a bone of a patient (Col. 7, lines 49-57; Col. 11, lines 45-50; Fig. 8, steps 800-802), computing a second set of data based upon the first set of data (Col. 7, lines 59-65; Fig. 8, steps 800, 802, 808, 810); and manufacturing said prosthesis to include an acetabular cup and an attachment part extending therefrom (Fig. 8, steps 814, 824; Fig. 4A, acetabular cup 86, attachment part corresponds to elements 84, 72 or 78), wherein said manufacturing step includes the step of forming said attachment part based on the second set of data (Fig. 8, steps 806, 808-824; Col. 6, lines 50-65; Col. 5, line 65 – Col. 6, line 5).

As for claim 2, **Kennedy** discloses,

- said second set of data defines in three dimensions said attachment part (Col. 11, lines 55-61).

Art Unit: 2125

As for claim 3,

- said attachment part comprises a flange extending from said acetabular cup (Fig. 4A, element 84; Col. 13, lines 22-25, i.e., head 84 has an aperture which receives neck portion 80, and **socket type joint with acetabular shell and liner 86**, please note that flange is a rim, edge, rib or collar used to strengthen an object, hold it in place, or attach it to another object), and said flange has defined therein a number of throughholes configured to receive an anchoring element (Fig. 4A, element 84 contains an aperture to anchor element 82).

As for claim 4,

- forming said attachment part to include a bone-facing surface and a tissue-facing surface, and forming said tissue-facing surface to be a partial facsimile of a surface of said bone (Figs. 5-7, implant topology 84 and medullary canal model 82; Col. 13, line 38-43; please note that the implant would be attached to an actual bone and part of the implant would face a tissue-facing surface such as any other part of a body not including bone).

As for claim 5,

- said manufacturing step further includes the step of forming said bone-facing surface to possess a shape complementary to a portion of the surface of said bone (Col. 13, lines 38-40 and lines 16-26; Fig. 4A, elements 72, 82, 84 and 86).

As for claim 7, the same citations applied to claims 4 and 5 apply as well for this claim.

Regarding claim 9, the same limitations applied to claim 1 above apply as well for claim 9, please note that “making a prosthesis for a joint socket” reads on (Fig. 4A, elements 82, 84, 86; Col. 13, lines 22-25, i.e., head 84 has an aperture which receives neck portion 80, and **socket type joint with acetabular shell and liner 86**).

As or claims 10-13, the same citations applied to claims 2-5 above apply as well for these claims.

As for claim 15, the same citations applied to claims 4 and 5 above apply as well for this claim.

As for claim 17,

- said manufacturing step includes manufacturing said acetabular cup from pre-determined data (Col. 6, lines 50-65, i.e., to replace the acetabulum; Fig. 8, step 824).

Regarding claim 18, **Kennedy** discloses, a method of making an acetabular prosthesis (Fig. 4A, acetabular 86) comprising the steps of:

- acquiring a first set of data defining in three dimensions at least a portion of a bone of a patient (Col. 7, lines 49-57; Col. 11, lines 45-50; Fig. 8, steps 800-802), computing a second set of data based upon the first set of data (Col. 7, lines 59-65; Fig. 8, steps 800, 802, 808, 810); and manufacturing said prosthesis to include an acetabular cup and an attachment part extending therefrom (Fig. 8, steps 814, 824; Fig. 4A, acetabular cup 86, attachment part corresponds to

elements 84, 72 or 78), wherein said manufacturing step includes the steps of: forming said attachment part based on the second set of data (Fig. 8, steps 806, 808-824; Col. 6, lines 50-65; Col. 5, line 65 – Col. 6, line 5); forming said attachment part to include a bone-facing surface and a tissue-facing surface, and forming said tissue-facing surface to be a partial facsimile of a surface of said bone (Figs. 5-7, implant topology 84 and medullary canal model 82; Col. 13, line 38-43; please note that the implant would be attached to an actual bone and part of the implant would face a tissue-facing surface such as any other part of a body not including bone).

As for claims 19-20, the same citations applied to claims 2 and 3, respectively, apply as well for claims 19-20.

Regarding claim 22, **Kennedy** discloses, an acetabular prosthesis, comprising:

- an acetabular cup (Fig. 4A, element 86); and a flange attached to said acetabular cup (Fig. 4A, element 84; Col. 13, lines 22-25, i.e., head 84 has an aperture which receives neck portion 80, and **socket type joint with acetabular shell and liner 86**, please note that a flange is a rim, edge, rib or collar used to strengthen an object, hold it in place, or attach it to another object; the head 84 includes a socket type joint with acetabular 86), said flange is prepared by a process including the steps of: acquiring a first set of data defining in three dimensions at least a portion of a bone of a patient (Col. 7, lines 49-57; Col. 11,

lines 45-50; Fig. 8, steps 800-802), computing a second set of data based upon the first set of data (Col. 7, lines 59-65; Fig. 8, steps 800, 802, 808, 810); and manufacturing said flange based upon the second set of data (Fig. 8, steps 806, 808-824; Col. 6, lines 50-65; Col. 5, line 65 – Col. 6, line 5).

As for claims 23-26, the same citations applied to claims 2-5 above apply as well for claims 23-26. Please note that the flange is part of the implant topology as shown in Fig. 4A, elements 84 and 86, Col. 13, lines 22-25, i.e., head 84 has an aperture which receives neck portion 80, and **socket type joint with acetabular shell and liner 86**).

As for claim 28, the same citations applied to claims 4 and 5 apply as well for this claim.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 14, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kennedy (5,360,446)** in view of **Gibbs (US 2003/0212459)**.

Kennedy discloses the limitations of claims 1, 9 and 13 above, but fails to disclose the limitations of claims 6, 14, and 27. However, **Gibbs** discloses such limitations as follows:

Regarding claims 6, 14 and 27, **Gibbs** discloses,

- said attachment part possesses a cup interface end portion and a free end portion (Figs. 1-2, elements 32, 34, 36), and said forming step includes forming said attachment part with a uniform thickness extending from said cup interface end portion to said free end portion (Fig. 1, element 34, 34B, please note that part 34 has a uniform thickness as shown in Fig. 1).

Therefore, it would have been obvious to a person of the ordinary skill in the art at the time the invention was made to combine the prosthesis design system of **Kennedy** with the system for an acetabular prosthesis of **Gibbs** because it would provide an improved acetabular prosthesis system to replace an acetabulum that allows trailing for a shell component wherein the trial shell is operable to be selectively oriented (**Gibbs**, Page 2, [0013]).

3. Claims 8, 16, 21 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kennedy (5,360,446)** in view of **DiGioia, III et al. (US 205,411)**

Kennedy discloses the limitations of claims 1, 9, 18 and 22 above but fails to disclose the limitations of claims 8, 16, 21 and 29. However, **DiGioia** discloses such limitations as follows:

Regarding claims 8, 16, 21 and 29, **DiGioia** teaches,

- acquiring a third set of data defining in three dimensions other bone structure of the patient, at least some of said other bone structure contralaterally corresponding to said bone of the patient, wherein: said manufacturing step includes the step of arranging an angular orientation of said acetabular cup relative to at least one of said attachment part and the bone of the patient based on said third set of data (Col. 10, lines 1-8 and lines 19-31, i.e., the computer system uses the geometric model 90 of the patient's pelvis, the model 92 of the patient's femur, the model 94 of the acetabular cup and model 96 of the femoral implant to perform simulated biomechanical testing of the acetabular cup... the important parameters in evaluating the prosthetic range of motion are ... the position, including angular orientation of the acetabular cup).

Therefore, it would have been obvious to a person of the ordinary skill in the art at the time the invention was made to combine the prosthesis design system of **Kennedy** with the system of **DiGioia** because it would provide an improved system to precisely determine an optimal size and position of artificial components in a joint to provide a desired range of motion of the joint (**DiGioia**, Col. 4, line 67 – Col. 5, lines 1-2).

Conclusion

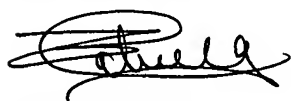
4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning communication or earlier communication from the examiner should be directed to Zoila Cabrera, whose telephone number is (571) 272-

Art Unit: 2125

3738. The examiner can normally be reached on M-F from 8:00 a.m. to 5:30 p.m. EST (every other Friday).

If attempts to reach the examiner by phone fail, the examiner's supervisor, Leo Picard, can be reached on (571) 272-3749. Additionally, the fax phones for Art Unit 2125 are (703) 872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist at (703) 305-9600.

A handwritten signature in black ink, appearing to read 'Zoila', with a stylized flourish at the end.

Zoila Cabrera
Patent Examiner
11/12/04